This Appeals Brief as required by 37CFR 41.37 is in response to the Final Office Action in this case

Application No.: 10/604469

Real Party of Interest:

1. Iftikhar Khan

Group Art Unit: 3763

Examiner: Theodore Stigell

Title: Orotracheal Suction System

Filing date: 7/23/03

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Related Appeals and Interferences.

There are no appeals or interferences

STATUS OF CLAIMS

Claims 10,13,14,16, 17 were rejected and are being appealed.

Claims 1-9,11, 12 and 15 have been cancelled

STATUS OF THE AMENDMENTS

No amendments made subsequent to final rejection

SUMMARY OF THE CLAIMED SUBJECT MATTER

An apparatus for suctioning the orotracheal area to remove obstructive material from the oropharynx and trachea of a patient. The system is comprised of a catheter having a distal end and a proximal end, and a length sufficient to engage the oropharynx and distal bronchi of the patient at the catheter distal end; a seal at the distal end of the catheter;an extension tubing operable for attachment to the catheter proximal end and extending a distance away from the patient's head and mouth; and a reservoir operable to connect to the extension tubing and to collect the obstructive materials using a vacuum source. The reservoir comprises an entry compartment and a second compartment, wherein the compartments are separated by a grid operable to prevent obstruction of the vacuum by the obstructive material.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 10,13-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatenable over Pell et al. (4,850,348) in view of Wood (GB 2,220,357).

2.Claims 10,13-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in review of Wood (GB)2,220,357 and unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in review of Joseph (US Pat no 5819723)

Arguments

1. Claims 10,13-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatenable over Pell et al. (4,850,348) in review of Wood (GB 2,220,357).

In response to the assertion by the examiner that "the structure defined in claim 10 can be used in a materially different process such as suctioning the mouth or a wound in the body." No Sir, it cannot. The said structure defined in claim 10 (the suction catheter) is beveled at the tip ; it is designed and intended for suctioning the mouth, oropharynx, supraglottic spaces, subglottic spaces, trachea, and proximal and distal bronchi of large debris and fluid. My device cannot be used for "a wound on the body". Woods' device is a simple, obsolete wound suction. I know because I have actually used wound suctions on patients which are the same as Woods' device and that are far superior to what Woods' describes in his patent. It is clear the examiner because of his profound lack of medical knowledge does not know what is a "wound on the body". The examiner did not define a wound on the body. One who was rendering opinions about what "ordinary skill"in this art is, would know that many "wounds on the body" have small delicate structures; nerves,

tendons, micro-arterial and venous structures and connective tissues which would be destroyed by our orotracheal suction to be applied to them. A suction intended for use in the oropharynx and trachea cannot be applied to any "wound on the body." If Mr. Stigell understood what ordinary skill in the art this comparison would not be made. Suctioning a surgical or traumatic wound on the body, given the size and the particular structures involved, is a completely different enterprise requiring specific suctioning catheters and equipment which are protected by different patents even though they are providing an apparatus which suctions. It depends on where the wound is, what has been injured, how deep the wound is and what are the particular fine structures involved-none of which Mr. Stigell takes into account because he has no knowledge or training in this art.

There are multiple inventions which are inherently the same device, but used for very different applications even though they have the same basic structure. A Foley catheter is basically a catheter with a balloon. A Swanz-Ganz is basically a catheter with a balloon. A Fogarty catheter is basically another catheter with a balloon which is used to remove arterial and venous obstruction. The Foley is used to drain the bladder. A Swan-Ganz is used to measure pulmonary capillary wedge pressure, as well as left ventricular end diastolic pressure (LEDP) and cardiac output. area of One with ordinary skill in the art could easily come up with the Swan Ganz and the Fogarty Catheter since they are essentially the same structure and device as the Foley-flexible catheters with balloons at the distal ends. The Swan-Ganz catheter and Fogarty are even used in the same organ system-the arteriovenous system; I am willing to accept that my invention is not patentable under 35 U.S.C. 103(a) if the examiner can invalidate the patents of the Swanz-Ganz

and Fogarty catheters which are essentially the same devices. How more obvious and similar can these devices be, yet somehow they achieved patent protection.

It defies reason that Ted Stigell can render opinions about what individuals with "ordinary skill" in this art could develop, when he has no training or skill in this art, yet these catheters with balloons have achieved been awarded patents but they are essentially the same device. Mr. Stigell did not have any answer to this in the previous communications.

Let us look carefully at the basis of the claims rejections to see why there is no basis for any of the rejections. The quotation of 35 U.S.C. 103(a) "which form the basis for all obviousness rejections set forth in the office action" as the examiner states. It relies heavily on the fact that the examiner can comprehend what ordinary skill in the art he or she is examining is. From viewing all the communications these examiners have written it is clear that they do not know what ordinary skill in this art is and will not. A person with ordinary skill in this art is someone who is allowed to actually use such a devices to perform the life saving procedures at critical times when a patient needs it. It requires that the person with this ordinary skill has dissected the structures on a human body and studied the organs and vascular and pulmonary structures to the highest degree as taught in United States medical schools. It would require that person with such "ordinary skill" to excel in medical school to be selected for training which few of the

graduates can attain. It would require that person be allowed to perform these procedures on live patients, where one is attempting to access the pulmonary system in an emergent manner to relieve acute airway obstruction. This would require to person of "ordinary skill" to be selected for emergency medicine or thoracic surgery training. It would require this person of "ordinary skill" to peform at a high level for 110-130 hrs/wk to be allowed the privilege to handle these devices at critical times to save patients lives. To still perform these tasks in the middle of the night, even though you have been awake for 40hrs. There is no substitute for actually having the experience, skill and medical knowledge which comes from over 10 years of the most intensive medical training a person can experience. Ted Stigell cannot learn this by reading what other peoples patents are and attending examiner academy. The examiner cannot hyperspace into this position and give an opinion on what ordinary skill in this art when he has absolutely no comprehension of what that person's knowledge and skill level is. It negates the basis for all of his rejections because in no way can understand what ordinary skill in this art even is, at his current level of education and training. One cannot go from zero medical training to understanding the limitations, functions and nuances of medical devices and procedures that it takes some with "ordinary skill" in the art 10 years of intensive medical training to achieve.

I asked the examiner to present his training and education and reasons he would know what "ordinary skill in the art" of emergency medicine and thoracic surgery, and specifically relieving acute airway obstruction with invasive devices. Based on the result of this appeal, I am very willing to take matter the matter to federal court

where the examiners can state explicitly how they achieved understanding of "ordinary skill" in this art to render an opinion on what a person with "ordinary skill" would be able to develop based on their cited previous art. I will also try this matter, in civil court, to reclaim lost time and wages regarding dealing with the examiners in this case. The only place that exists to expose this fraud at the USPTO , caused by these examiners, is in federal and civil court.

Director Doll has education in chemistry and physics, and a master of science from the Pennsylvania State University in physical chemistry. He at least could render an opinion in the field he examined including, hydrometallurgy and inorganic chemistry, because he could at least understand what ordinary skill in that art is and his opinion would be respected. I cannot render opinions on what ordinary skill in the art of designing new O rings on the space shuttle. I have no training or education in aerospace engineering. It would ridiculous. In the same light, these examiners have no basic, much less graduate medical training or even basic anatomical training one would receive in a human anatomy in medical school. They cannot render any opinion on what ordinary skill in this art of these invasive medical devices until they achieve that level of knowledge and procedural skill regarding these devices which comes as mentioned with over 10 years of medical and surgical training and education-going to examiner academy does not suffice. If they have any medical or surgical training that would allow them to legally place a band-aid on a patient, much less an invasive medical device in a humans' oropharynx and lungs, please let them state it for the record.

The statement made by the examiner in his last final rejection of 2/12/08 stating

"it is clear that the system would work just as well with a standard suction canister as it would with the claimed reservoir. How exactly does Mr. Stigell know that? Has he used different suction systems before? (No) Has he connected the tubing and seen what the diameter is and flow rate that standard that a standard container can achieve ?(No). Has he seen suction tubing obstruct when trying to remove foreign material over the glottis of a patient (No). Where is the glottis , Mr. Stigell? One with ordinary skill in the art or someone rendering an opinion about persons' with ordinary skill, which Mr. Stigell is doing, would know the answer to these questions and he sadly does not.

My previous patent attorney presented that the system can be used with a standard container. It is feasible, but not preferable. I can state here for the record that it is not preferable to use my suction system with a standard canister because the debris may obstruct the inlet and outlet source to the vacuum. It is preferable to use the suction system.

2. Claims 10,13-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in review of Wood (GB)2,220,357, and unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in

review of Joseph (US Pat no 5819723)

In this case, the examiner has rejected claims 10,13,14 16-17 are unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in review of Wood (GB)2,220,357 and unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in review Joseph (US Pat no 5819723). These rejections will be handled separately below as the examniners' requested in the communication from 11/18/09.

Firstly, with regards to Pell's device; Pell's device as mentioned before has no function to suction the oropharynx or trachea and as previously presented has no design to capture debris into a receptacle. It is a tube used for endotracheal intubation for use with a ventilator and as a positioning device in the mouth. It has no structure or mechanical design to allow for any suction in any body part.

Someone with "ordinary skill" in the art cannot think of using this device for any other purpose or they would have seriously less than even ordinary skill, or better stated no skill or dangerous skill in the art. The examiner cannot comprehend this because he has zero skill or knowledge in the art and cannot possibly make determinations of what a person with ordinary skill in the art would be able to fashion based on the devices of Pell in view of Wood, or Pell in view of Joseph.

Pell again does not disclose any of the limitations I have disclosed. Mr. Stigell makes blanket statements such as "Pell discloses most of the limitations

recited by the applicant." How exactly does Pell do this? His device is for endotracheal intubation and ventilation. It is not intended for or have limitations which extend to a suction system to remove particulate forcign debris Mr. Stigell does not understand these devices or has he ever personally used such devices. There is only so much you can garner from reading other pcoples ideas and looking for similarities. I could then invalidate every vascular surgical device because it resembles a garden hose because they both carry fluid, using the examiner's logic. In light of the fact that the devices I have mentioned (Fogarty, Swan-Ganz, and Foley catheter) are essentially the same device and even used in the same organ systcm, his reasoning is flawed. I cannot take Mr. Stigell through 10 years of medical and surgical training to understand these devices, how they are used and their exact limitations. Therefore claims 10, 13-14, and 16-17 should not to be rejected under 35 U.S.C.

I know from his description of these devices that Mr. Stigell does not know what the devices he is citing actually do and therefore cannot understand their limitations. He does not understand if Pell's device can even be employed with assist control or SIMV ventilation or what happens when foreign material will obstruct the lumen of Pell's device. He certainly cannot comprehend what someone with ordinary skill in the art could develop up in light of Pell's device.

Argument to rejection of Claims 10,13-14, and 16-17 under 35 U.S.C. 103(a) as being unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in

review of Wood (GB)2,220,357:

He writes that Wood discloses "a suction catheter system that is designed to remove blood, irrigation liquid" during a surgical procedure. Mr. Stigell does not understand any of the limitations of this device. One with ordinary skill in this art would understand that you cannot take a marginal wound-vacuum suction, which is what Wood's device is, and somehow conceive of my device, with knowledge of Pell's device. The human anatomic structures a wound suction contacts are particular and delicate; they include fine vascular and neural structures that are fractions of a millimeter in diameter. It also depends on the size of the wound. The uses, designs and limitations of Woods' device are not for the oropharynx, supraglottic and subglottic spaces or the tracheal or distal bronchial structures. It is like looking at a shop-vac in your garage and using it to invalidate the patent protection of all suctions that have specific medical uses in particular areas of the human anatomy. That is how related Woods' device is to my device. Again as stated, Mr Stigell does not have the knowledge or technical skill in this art to render and opinion on what someone with ordinary skill in this art would be able to construct in light of these unrelated devices he has cited so his rejections are not valid and should be withdrawn.

Argument to Claims 10,13-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in review of , in review Joseph (US Pat no 5819723):

The device from Joseph as I mentioned ad nauseum previously to the examiner, functions to remove a few (if even that) milliliters of tracheal secretions to improve tracheal hygiene in intubated patients. It is desgined to irrigate the area of the proximal trachea only to remove excessive accumulation of fluid in the proximal trachea only. It has no designed apparatus to allow for suctioning and more importantly it is not designed for any removal of debris from the distal trachea or the oropharynx. Someone with ordinary skill cannot in any conceivable way look at Joseph's device , with knowledge of Pell's device and in any reasonable way develop a functional device to clear the oropharynx, proximal trachea, distal trachea, proximal bronchi and distal bronchi of foreign debris and large volumes of fluid which has been aspirated.

I present for the appeals board why I have ordinary skill in this art and can make the asscrtions about what a person of ordinary skill could develop. I graduated at the top of my medical school class from a United States medical school. I was selected to the medical honor society. I scored a 99% on my US medical licensing exam, one of the most difficult professional licensing exams in the world. I served as the chief of my residency. I was selected to surgical and emergency medicine training programs at two of the top hospitals in our nation. I practice this art every day of my life. I have studied this art at the highest level through 10 yrs of graduate medical training and now practical experience as an attending physician in some of the top hospitals in the world.

I can estimate what ordinary skill in this art, as well as extraordinary skill. What did I know about ordinary skill in this art after obtaining an undergraduate

degree in biology(nothing). What did I know about ordinary skill in this art after obtaining a Doctor of Medicine degree? (at least something, but not ordinary skill) I covered the physiology and anatomy of the human body with rigourous detail and was able to assist physicians in implanting these devices in live patients in the operating room. What did I know about ordinary skill in this art after training for 6 years in the intensive care unit, emergency department, and operating room actually handling and using the devices to save critically ill patients? (ordinary skill in the art). What do I know now that I am board certified by the American Board of Emergency Medicine and now selected as a fellow of the American College of Emergency Physicians (more than ordinary skill in the art). It is a difficult, highly selective process that takes 13 yrs after starting medical school. Mr. Stigell cannot conjecture about what ordinary skill in this art is, and what a person with ordinary skill in the art might be able to develop or not, when he himself has zero skill, knowledge or actual training in this art. I welcome him to try to start the process. The basis for all of his rejections is therefore invalid and the rejections should be all removed. It has all been a house of cards- I wish I had recognized it earlier.

I am very serious about this next point. I will try the matter in federal court, and Mr. Stigell can discuss how exactly he has ordinary skill in the art so this fraud can be exposed. I will also recover immense lost time and wages in civil court against these examiners and for what has been stated above and the reasons below.

My patent attorney and many others have said, the goal is for the examiner to prolong this as long as possible, almost always issuing a final rejection and charging another fee.

The examiner ,Ted Stigell, also sent me a duplicate request for changes to the drawings after I had sent him the changes 3 months prior. The process is already frustrating and this lack of competence makes it more so. Lest he forget, I documented in an email to him which is saved and to Frederick Schmidt, the director of the entire unit and my attorneys. I called Nick Luchesi, but he does not respond to any phone calls, ever, which has been mentioned to Director Schmidt. Again, no mention of this point in the last communication.

This device could save many citizens here and soldiers abroad dying needlessly from acute aspiration and lung injury caused by airway obstruction. I developed my device when a patient before was dying from acute airway obstruction and there was no device available to quickly remove the obstruction. I thankfully was at a large tertiary care hospital, which is one of the best staffed and equipped on earth, so we were able to take the patient to surgery and relieve the obstruction. Very few hospitals have this capability and I want them to have it because it may be you at one of these small hospitals dying from acute airway obstruction and I would like this equipment available to help these providers that do not always have the support and training to deliver this service.

Claims Appendix

10. An orotracheal suction system for suctioning obstructive material from the oropharynx and trachea of a patient, the system comprising: a catheter having a distal end and a proximal end, a diameter of from about 0.5 Fr to about 15 Fr, and a length sufficient to engage the oropharynx and distal bronchi of the patient at the catheter distal end; a seal at the distal end of the catheter;an extension tubing operable for attachment to the catheter proximal end and extending a distance away from the patient's head and mouth; and a reservoir operable to connect to the extension tubing and to collect the obstructive materials using a vacuum source; wherein the reservoir comprises an entry compartment and a second compartment, wherein the compartments are separated by a grid operable to prevent obstruction of the vacuum by the obstructive material.

13. The orotracheal suction system of Claim 10, wherein the reservoir comprises a removable disc to empty the obstructive material from the reservoir.

14. The orotracheal suction system of Claim 10, wherein the catheter and extension tubing have a diameter to accommodate an obstructive food bolus.

16. The orotracheal suction system of Claim 10,

wherein the seal comprises a balloon and wherein the catheter further comprises a balloon port to inflate the balloon.

17. The orotracheal suction system of Claim 10,

wherein the extension tubing has a length of from about 3 feet to about 5 feet.

Evidence Appendix Page

None

Related Proceedings Appendix Page

None

Thank You for consideration of this appeal.

Sincerely,

Iftikhar Khan MD, Fellow of the American College of Emergency Physicians